

**THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE  
PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:**

1. A pharmaceutical composition comprising:

an effective amount of a  $\beta$  (1-3)- $\beta$  (1-4) glucan, and

an effective amount of a botanical extract, or a pharmaceutically active agent.

2. The pharmaceutical composition according to claim 1, wherein the

composition comprises the botanical extract, and wherein the botanical extract is an

extract of Guarana, *Ginkgo biloba*, Kola nut, Goldenseal, Golo Kola, *Schizandra*,

Elderberry, St. John's Wort, Valerian and *Ephedra*, black tea, white tea, java tea,

garlic oil, fiber, green tea, lemon oil, mace, licorice, onion oil, orange oil, rosemary,

milk thistle, *Echinacea*, Siberian ginseng or *Panax ginseng*, lemon balm, *Kava kava*,

matte, bilberry, soy, grapefruit, seaweed, hawthorn, lime blossom, sage, clove, basil,

curcumin, taurine, wild oat herb, oat grain, dandelion, gentian, aloe vera, hops,

cinnamon, peppermint, grape, chamomile, fennel, marshmallow, ginger, slippery elm,

cardamon, coriander, anise, thyme, rehmannia, eucalyptus, menthol, schisandra,

withania, cowslip, lycium, or passion flower.

3. The pharmaceutical composition according to claim 2, wherein the botanical  
extract is an extract of oat grain.

4. The pharmaceutical composition of claim 3, wherein the botanical extract  
comprises avenanthramide.

5. The pharmaceutical composition according to claim 1, wherein the  
composition comprises the pharmaceutically active agent, and wherein the  
pharmaceutically active agent is selected from the group consisting of beta-sitosterol,  
caffeine, cafestol, D-limonene, kabweol, nomilin, oltipraz, sulphoraphane, tangeretin,  
folic acid, and menthol.

6. The pharmaceutical composition according to claim 1, wherein the  
composition comprises the pharmaceutically active agent, and wherein the  
pharmaceutically active agent is selected from the group consisting of an

antihistamine, a decongestant, a corticosteroid, a non-steroidal anti-inflammatory drug, a bronchodilator, a vasodilator, such as nitroglycerin, and a local anaesthetic.

7. The pharmaceutical composition of claim 6, wherein the vasodilator is  
5 nitroglycerin.

8. The pharmaceutical composition according to claim 1, wherein the  $\beta$  (1-3)  $\beta$  (1-4) glucan is derived from a cereal grain or a part of the cereal grain.

10 9. The pharmaceutical composition according to claim 8, wherein the cereal is selected from the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, a cultivar of corn, and a mixture thereof.

15 10. The pharmaceutical composition according to claim 1, wherein the  $\beta$  (1-3)  $\beta$  (1-4) glucan is a  $\beta$  (1-3)  $\beta$  (1-4) glucan composition having a purity of at least about 75%, and containing less than 10% ash impurities, less than 10% protein impurities, and less than 5% lipid impurities.

20 11. The pharmaceutical composition according to claim 10, wherein the  $\beta$  (1-3)  $\beta$  (1-4) glucan composition has a purity of at least about 92%, and contains less than 3.5% ash impurities, less than 3.5 % protein impurities, and less than 1% lipid impurities.

25 12. The pharmaceutical composition according to claim 10, wherein the cereal  $\beta$ -glucan composition has a clarity value of from about 5 to about 100 NTU.

13. The pharmaceutical composition according to claim 1, wherein the  $\beta$  (1-3)  $\beta$  (1-4) glucan is produced according to a method of isolating a  $\beta$  (1-3)  $\beta$  (1-4) glucan  
30 from a milled cereal grain or a milled part of the cereal grain, comprising:

- (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution to produce an extract containing at least about 0.4 weight percent  $\beta$  (1-3)  $\beta$  (1-4) glucan;

(ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2  $\mu\text{m}$  from said extract to produce a purified extract;

(iii) adding from about 10% to about 25% (w/w) of a  $\text{C}_1\text{-C}_4$  alcohol to the purified extract to precipitate the  $\beta$  (1-3)  $\beta$  (1-4) glucan, and

(iv) isolating the  $\beta$ (1-3)  $\beta$ (1-4) glucan.

14. The pharmaceutical composition according to claim 13, wherein in said step of adding (step iii) in said method, about 10% to about 20% (w/w) of an alcohol selected from the group consisting of methanol, ethanol and isopropanol, is used to precipitate the  $\beta$  (1-3)  $\beta$  (1-4) glucan from said purified extract.

15. The pharmaceutical composition according to claim 14, wherein about 10% to about 20% (w/w) of ethanol is used to precipitate the  $\beta$  (1-3)  $\beta$  (1-4) glucan from said purified extract.

16. The pharmaceutical composition according to claim 13, wherein said step of removing particulate material in said method comprises:

one, or more than one step of adding a flocculant, a coagulant or both a flocculant and a coagulant to said extract to coagulate particulate material having a particle size of greater than about 0.2  $\mu\text{m}$ , and removing coagulated material from said extract;

digesting starch material in said extract, and

filtering out particulate material having a particle size of greater than about 0.2  $\mu\text{m}$  from said extract to produce a purified extract.

17. The pharmaceutical composition according to claim 16, wherein in said step of digesting in said method, said starch material is digested with an enzyme.

18. The pharmaceutical composition according to claim 17, wherein prior to  
5 digesting said starch material, said alkaline solution is neutralized.

19. The pharmaceutical composition according to claim 18, wherein following the digestion of said starch material in said method, said enzyme is inactivated.

10 20. The pharmaceutical composition according to claim 19, wherein said enzyme is inactivated by acidifying the neutralized solution.

21. The pharmaceutical composition according to claim 17, wherein said enzyme is an amylase.

15 22. The pharmaceutical composition according to claim 21, wherein said amylase does not require a calcium cofactor.

23. The pharmaceutical composition according to claim 13, wherein the cereal is  
20 selected from the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, a cultivar of corn, and a mixture thereof.

24. The pharmaceutical composition according to claim 13, wherein the pH of the  
25 alkaline solution used in said method is from about 9 to about 10.

25. The pharmaceutical composition according to claim 13, wherein said step of extracting (step i) in said method is carried out over a period of from about 15 to about 45 minutes.

30 26. The pharmaceutical composition according to claim 13, wherein said step of adding (step iii) in said method is conducted at a temperature of from about 1°C to about 10°C.

27. The pharmaceutical composition according to claim 13, wherein said method further comprises one, or more than one step of dissolving the isolated  $\beta$  (1-3)  $\beta$  (1-4) glucan in an aqueous solution, precipitating the  $\beta$  (1-3)  $\beta$  (1-4) glucan by adding about 10% to about 25% (w/w) of the C<sub>1</sub>-C<sub>4</sub> alcohol to the aqueous solution, and  
5 isolating the  $\beta$  (1-3)  $\beta$  (1-4) glucan.